Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Proposed Maximum Residue Limit PMRL2015-22

Fludioxonil

(publié aussi en français)

14 July 2015

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2015-22E (print version)
H113-24/2015-22E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2015

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on crops included in the Bulb Vegetable Crop Group (Crop Group 3-07) and the Leafy *Brassica* greens Subgroup (Crop Subgroup 5B) to the product label of SWITCH® 62.5 WG Fungicide, containing technical grade fludioxonil and cyprodinil, is acceptable. The specific uses approved in Canada are detailed on the label of SWITCH® 62.5 WG Fungicide, Pest Control Products Act Registration Number 28189. MRL consultation for the cyprodinil present in SWITCH® 62.5 WG Fungicide is being conducted under a separate action.

The evaluation of this fludioxonil application indicated that the end-use product has merit and value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for fludioxonil is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRLs, to replace or be added to the MRLs already established for fludioxonil, are as follows.

Table 1 Proposed Maximum Residue Limits for Fludioxonil

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile	15	Leafy *Brassica* greens (Crop Subgroup 5B)[2]
		7.0	Green Onion Subgroup (Crop Subgroup 3-07B)[3]
		0.2	Bulb Onion Subgroup (Crop Subgroup 3-07A)[4]

[1] ppm = parts per million

[2] This MRL is proposed to replace the established MRL of 8.0 ppm for fludioxonil in/on mustard greens, and the established MRL of 0.01 ppm for fludioxonil in/on broccoli raab, bok choy Chinese cabbages, collards, kales, mustard spinach, and rape leaves.

[3] This MRL is proposed to replace the established MRL of 0.02 ppm for fludioxonil in/on fresh Chinese chive leaves, fresh chive leaves, leeks, tree onion tops, and Welsh onion tops. An MRL of 7.0 ppm is already established for green onions.

[4] This MRL is proposed to replace the established MRL of 0.02 ppm for fludioxonil in/on Chinese onions, garlic, great headed garlic, and potato onions. The commodity name for the MRL of 0.02 ppm established for shallots will be revised to shallot bulbs to reflect current terminology. An MRL of 0.2 ppm is already established for dry bulb onions.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for fludioxonil in Canada with corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Leafy *Brassica* greens (Crop Subgroup 5B)	15	10	10 (Mustard greens)
Green Onion Subgroup (Crop Subgroup 3-07B)	7.0	7.0	Not established
Bulb Onion Subgroup (Crop Subgroup 3-07A)	0.2	0.5	0.5 (Onion, bulb)

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for fludioxonil up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data for fludioxonil in dry bulb onions and green onions were reassessed within the framework of this petition, and residue data for mustard greens were reviewed to support the domestic use of SWITCH® 62.5 WG Fungicide on crops included in the Bulb Vegetable Crop Group (Crop Group 3-07) and the Leafy *Brassica* greens Subgroup (Crop Subgroup 5B).

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for fludioxonil was based upon the residue data on file, the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs.

Table A1 Summary of Field Trial Used to Support MRLs

Commodity	Application Method/ Total Application Rate (kg a.i./ha)[1]	Preharvest Interval (days)	Maximum Residues (ppm)	Minimum Residues (ppm)
Mustard Greens	Foliar/ 0.96-1.02	6-8	7.74	0.06
Green Onions	Foliar/ 1.1	7	6.27	0.119
Bulb Onions	Foliar/ 0.73-1.1	6-7	0.106	<0.02

[1] kg a.i./ha = kilograms of active ingredient per hectare

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of fludioxonil in the listed crops. Residues of fludioxonil in these commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.